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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/910,703	07/20/2001	Bruce J. Barclay	VASC 1020-2	2083
22470	7590	05/22/2006	EXAMINER	
HAYNES BEFFEL & WOLFELD LLP P O BOX 366 HALF MOON BAY, CA 94019			PELLEGRINO, BRIAN E	
			ART UNIT	PAPER NUMBER
			3738	
DATE MAILED: 05/22/2006				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/910,703

Applicant(s)

BARCLAY ET AL.

Examiner

Brian E Pellegrino

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 February 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) See Continuation Sheet is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 3,4,8,9,19-22,25,26,38-40,42,74-76,78,102,104,108,112 and 114-116 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

Continuation of Disposition of Claims: Claims pending in the application are 3,4,8,9,19-22,25,26,38-40,42,74-76,78,102,104,108,112 and 114-116.

BRIANE PELLEGRINO
PRIMARY EXAMINER



DETAILED ACTION

Claim Objections

The numbering of claims is not in accordance with 37 CFR 1.126 which requires the original numbering of the claims to be preserved throughout the prosecution. A new claim 114 has been presented, with now 2 claims with the number 114. When new claims are presented, they must be numbered consecutively beginning with the number next following the highest numbered claims previously presented (whether entered or not). Misnumbered new claims 114,115 have been renumbered 115,116 respectively.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 3,4,9,25,26,38-40,74-76,102,108,112,114-116 are rejected under 35 U.S.C. 103(a) as being unpatentable over Herzog et al. (WO 98/08482) in view Razavi (5676685). Herzog et al. disclose a prosthesis in the form of a stent, a sleeve having an interior surface that houses the stent and spaces not occupied by the coiled body, and a NO generator within the sleeve interior, page 7, lines 7,8, page 14, lines 6-10,27-29. The examiner is interpreting the claimed elements "open spaces" in this way: since Herzog discloses pockets or grooves or depressions in the stent body, it can be construed as open spaces in the body. Claims in a pending application should be given their broadest reasonable interpretation. *In re Pearson*, 181 USPQ 641 (CCPA 1974). See also *In re Morris*, Fed. Cir. 1997 127 F3d 1048, 1054,1055. Herzog also discloses a method of delivering the agent (NO generator) to the target site is an anti-proliferative

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or anti-restenotic agent, since it inhibits restenosis, page 9, lines 16-23. The stent can be made of metal, page 11, line 22. Herzog also discloses biodegradable polymers can be used to control rates of delivery of NO, page 12, lines 20,21. Herzog additionally discloses the sleeve material on the stent is porous, and substantially impervious to blood, page 12, lines 2-5. The agent can also be encapsulated, page 12, line 11. Herzog et al. also disclose that a delay-release material is used to control the release of the agent into the blood vessel, page 11, lines 26,27. However, Herzog et al. fail to disclose a coiled stent and coiled sleeve. Razavi shows (Fig. 11) a coiled body **12** with radially extending openings between the adjacent rings and coiled sleeve **14**. Razavi teaches that the coil design is advantageous in that it allows for easy removal if necessary, col. 4, lines 27-29. Razavi also teaches the coil body is removed or is movable relative to the sleeve (col. 4, lines 19,30,31) and thus it can be construed the sleeve must be "oversized". It would have been obvious to one of ordinary skill in the art to substitute the stent design and sleeve of Razavi in the device of Herzog et al. in order to provide a stent with versatile delivery properties such that it reduces the trauma exerted on the patient's vessel walls when inserting and removing.

Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Herzog et al. (WO 98/08482) in view Razavi '685 as applied to claim 38 above, and further in view of Kropf '849. Herzog et al. in view Razavi is explained supra. However, Herzog as modified by Razavi fail to disclose the coiled body having spaced apart turns having gaps and the body having longitudinal side members and cross members. Kropf teaches a coiled stent with spaced apart turns and longitudinal members connected with

cross members, Fig. 5. Kropf teaches that the structural design enables the prosthesis to be deployed in a small profile reducing the likelihood of vessel trauma, col. 3, lines 8-13. It would have been obvious to one of ordinary skill in the art to substitute the stent design of Kropf in the stent of Herzog as modified by Razavi in order to provide a stent with good flexibility and a small profile for delivery with greater vessel coverage.

Claims 19-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Herzog et al. (WO 98/08482) in view of Razavi '685 as applied to claim 38 above, and further in view of Ragheb et al. '904. Herzog in view of Razavi is explained supra. However, Herzog as modified by Razavi do not disclose the use of two agents or the rates of use of them. Ragheb also teaches the use of first and second dispensable agents, col. 5, lines 58,59,63 and col. 6, lines 3-14. It would have been obvious to one of ordinary skill in the art to use a second agent as taught by Ragheb with the stent of Herzog as modified by Razavi, such that the device has enhanced capabilities and multiple treatment capabilities. Regarding claim 22, it would have been an obvious matter of design choice to modify the ability of the stent to release at least half of a first agent before a second is released, since applicant has not disclosed that using any set amount of one over another provides any advantage, or solves a stated problem, or is used for any particular purpose. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with the rates and amounts taught by Ragheb or the claimed at least half of first agent in claim(s) 22 because both designs perform the same function of releasing agents into the patient.

Claims 42,78 are rejected under 35 U.S.C. 103(a) as being unpatentable over Herzog et al. (WO 98/08482) in view of Razavi '685 as applied to claims 38,74 above, and further in view of Khosravi '054. Herzog as modified by Razavi is explained supra. However, Herzog in view of Razavi fail to disclose the porous sleeve is PTFE. Khosravi teaches the sleeve material covering the stent is made of PTFE, col. 5, lines 9,10. It would have been obvious to one of ordinary skill in the art to substitute porous polymers and use PTFE as a sleeve as taught by Khosravi with the stent of Herzog as modified by Razavi since it is known to select a known material on the basis of its suitability for the intended use as a matter of design choice.

Response to Arguments

Applicant's arguments with respect to claims 38 and 74 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not


mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Pellegrino whose telephone number is (571) 272-4756. The examiner can normally be reached on Monday-Thursday from 7am to 4:30pm. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott, can be reached at (571) 272-4754. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

TC 3700, AU 3738


BRIANE PELLEGRINO
PRIMARY EXAMINER